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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/227,749	01/08/1999	BRIAN J. BALIN	10062-1	7756

7590 03/02/2004

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EXAMINER

PESELEV, ELLI

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 03/02/2004

36

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/227,749

Applicant(s)

BALIN ET AL

Examiner

Elli Peseev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Claims 31-32 and 35-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 31 and 32 are substantial duplicate.

Claims 34 and 35 are substantial duplicates.

Note that terms "anti-microbial agent" (claim 31) and "antibiotic" (claim 32) have the same scope.

Claims 31-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons set forth in the Office Action of July 11, 2003.

Applicant's arguments filed in the amendment of November 17, 2003 have been considered but have not been found persuasive.

The abstract by Loeb et al has been considered but has not been found persuasive. The abstract states that "Therapy with doxycycline and rifampin may have a therapeutic role in patients with mild to moderate AD". However, the abstract states that more research is needed to investigate these agents. Further, the instant claims have not been limited to the treatment of patients with mild to moderate AD but encompasses patients with severe AD.

Claims 31-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shor et al (U.S. Patent No. 5,424,187) in combination with Koskiniemi et al (Eur. Neurol. 1996; 36:160-163) for the reasons set forth in the Office Action of July 11, 2003.

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Applicant's arguments filed in the amendment of November 17, 2003 have been considered but have not been found persuasive.

First, the amendment filed is improper in that it fails to set forth a copy of all the pending claims. Also, it was known in the art at the time the instant invention was made that Chlamydia infection was associated with Alzheimer's disease as disclosed by Mitchell et al (U.S. Patent No. 6,664,239) in column 30, lines 28-51).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 31-38 are rejected under 35 U.S.C. 102(a) as being anticipated by Mitchell et al (U.S. Patent 6,664,239).

Mitchell et al disclose the treatment of Alzheimer's disease with antibiotics or antibiotics in combination with anti-inflammatory agents (see, for example, claims 1, 9, 31 and 35).

Claims 31-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell et al (U.S. Patent No. 6,664,239).

Mitchell et al disclose the treatment of Alzheimer's disease with antibiotics or antibiotics in combination with anti-inflammatory agents but do not disclose all the specific antibiotics encompassed by the instant claims. However, a person having ordinary skill in the art at the time the instant invention was made would have been

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motivated to substitute one well known antibiotic for another in the method disclosed by Mitchell et al because such a person would have expected similar results.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 9.00-5.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev


ELLI PESELEV
PRIMARY EXAMINER
GROUP 1200